UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,227	07/02/2007	Paul Kemp	DFBP.075US	5775

32425 7590 05/26/2010
FULBRIGHT & JAWORSKI L.L.P.
600 CONGRESS AVE.
SUITE 2400
AUSTIN, TX 78701

EXAMINER	
EPPS -SMITH, JANET L	
ART UNIT	**PAPER NUMBER**
1633	
MAIL DATE	**DELIVERY MODE**
05/26/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,227	KEMP ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Smith	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28 and 37-62* is/are pending in the application.

4a) Of the above claim(s) *52-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28 and 37-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6-11-08; 11-07-2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-28 and 37-51 in the reply filed on 03/30/2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 52-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 03/30/2010.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-28 and 37-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leek et al. (WO 2002/072113A1) in view of Herlyn et al. (US20040031067A1), Drohan et al. (US7196054) and Harichian et al. (US20020018757).

5. The instant claims are drawn to a wound healing composition comprising living cells within a support matrix, in which the cells have a wound healing phenotype, and in which the composition is single-layered and *has been incubated for up to about 8 days*

to allow development of the wound healing phenotype. The cells are mammalian, substantially fibroblast, dermal fibroblast, and substantially excludes keratinocytes.

6. Leek et al. discloses a composition that comprising cells capable of reducing fibrosis and scarring in the process of wound healing, see abstract.

7. At page 3, lines 11-29, the following is disclosed:

> Thus according to the invention there is provided a composition comprising cells capable of reducing an inflammatory response caused by skin wounding and a cell delivery vehicle capable of delivering and maintaining the cells within a skin wound, wherein the cells are fibroblasts, the cell delivery vehicle is a matrix-forming material, and the composition is substantially free of other cell types, for use in the reduction of fibrosis and scar tissue during skin wound healing.
>
> By "substantially free of other cell types", it is meant that the fibroblasts comprise at least 90%, preferably at least 91, 92, 93, 94, 95, 96, 97, 98 or 99%, of the cells. Alternatively, the composition may be completely free of cell types other than fibroblasts.
>
> The composition at the time of incorporation of living cells may be free, or substantially free, of pre-formed matrix material. Matrix-forming material exists in a pre-matrix constitution in the composition but has the ability to form a scaffold or matrix around the cells in the composition.

8. This passage describes the compositions of Leek et al. as comprising cells having a wound healing phenotype, wherein the cells are fibroblast, and wherein cells are in a matrix-forming cell delivery vehicle. The composition is substantially free of other cell types, and comprises at least 90% fibroblast. Additionally, the matrix or scaffold forms around the cells in the composition. Page 5, lines 3-6 recites the following:

> The fibroblasts may be mammalian, preferably human. The invention provides that the cells could be allogeneic cells, i.e. the cells administered to a patient would be from a donor.

9. Leek et al. does not specifically teach wherein the living cells are single-layered, wherein the fibroblast are dermal fibroblast, wherein the compositions comprise a protease inhibitor, or wherein said inhibitor is aprotinin or tranexamic acid.

10. Herlyn et al. (US20040031067A1) teaches compositions for wound healing. In one embodiment Herlyn et al. describes a composition comprising a matrix containing a monolayer of human dermal fibroblast, see ¶ [0039].

11. Drohan et al. (US 7196054B1) teach supplemented fibrin matrix delivery systems useful as wound healing compositions. The compositions of Drohan et al. are described as follows, see abstract: “This invention provides supplemented and unsupplemented tissue sealants as well as methods for their production and use thereof. Disclosed are tissue sealants supplemented with at least one antibody. The composition may be further supplemented with various factors including, e.g. protease inhibitors and the like.

12. Harichian et al. (US 20020018757A1) Disclose a skin care compositions that function to stimulate collagen synthesis by fibroblast in the skin. The compositions comprise the protease inhibitor aprotinin.

13. The claims are replete with process steps, however they are directed to a product. Absent evidence to the contrary, the prior art is applied to the extent that it discloses the claimed product. As per MPEP § 2113 [R-1], “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability

is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).*

14. It would have been obvious to the ordinary skilled artisan to modify the teachings of Leek et al. with the teachings of Herlyn et al., Drohan et al., and Harichian et al. in the design of the instant invention. Absent evidence to the contrary, one of ordinary skill in the art would have been motivated to make this modification since the compositions disclosed in each reference are disclosed as useful in the treatment of various disorders associated with the skin. As per MPEP § 2144.06 "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) .

15. Regarding the rationale for combining prior art elements according to known methods to yield predictable results, all of the claimed elements were known in the prior art and one skilled in the art could have combined the element as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claim Rejections - 35 USC § 112

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

18. Claim 25 contains the trademark/trade name "Oliver™." Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a container suitable for transporting the wound healing composition of the instant invention and, accordingly, the identification/description is indefinite.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/
Primary Examiner, Art Unit 1633